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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,310	12/16/1997	ULF LANDEGREN	1209-121P	7960

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/21/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/981,310

Applicant(s)

Landegren et al

Examiner

Partner

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 5, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-10 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 5, 6, and 8-10 is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-5, 6, 8-10 are pending.

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Allowable Subject Matter

2. Claims 1, 5, 6, 8-10 define over the prior art of record and are allowed.

New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. .

The test kit of claims 3 and 4 are directed to the combination of three affinity reagents for the determination of a protein macromolecule, wherein the affinity reagent is a lectin, cofactor, receptor or nucleic acid.

Lectins bind to carbohydrates by definition and would not serve as an affinity reagent to detect a protein macromolecule. The claimed test kits that comprise three lectins, wherein the

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macromolecule is a protein, is not enabled for the detection of a protein macromolecule in a sample as lectins are not protein affinity reagents.

Cofactors are atoms or molecules specific for a different molecule and include zinc, copper, iron, heme, Fe-S, Mn, Mg, ATP, GTP, NAD to name a few. No combination of three affinity Cofactors for a single protein that would evidence binding sites in proximity to one another have been described in the instant specification. Any combination of three affinity Cofactors would not predictably bind to any protein macromolecule especially when the protein does not utilize a cofactor, or only has affinity for a single cofactor, not three. The instant specification has not enabled test kits that comprise three Cofactors that evidence affinity and simultaneously bind to the claimed genus of protein macromolecules, wherein the second and third Cofactors bind to different epitopes that are in proximity to one another to permit amplification or ligation of the oligonucleotide labels attached to the Cofactors. The instant specification has not provided guidance, nor teaches how any three Cofactors could be used to detect any protein macromolecule in a sample. The test kits that comprise three affinity reagents that are Cofactors are not enabled as they do not evidence the required functional limitations recited in the claims. No examples have been provided to define or show the missing information. The person of skill in the art would be required to perform undue experimentation to identify how any protein macromolecule could be detected using any combination of Cofactors, especially when the protein does not evidence natural binding characteristics for three different Cofactors, or have binding site sufficiently close to one another to permit the detection/amplification/ligation of

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the oligonucleotides conjugated to the three Cofactors. Kits that comprise three affinity Cofactors are not enabled for ~~the~~ detecting the recited genus of protein macromolecules.

Additionally the instant specification has not enabled the utilization of three receptors to simultaneously bind to a single protein macromolecule to detect the macromolecule in a sample. The instant specification has not described any protein macromolecules that would bind to three affinity receptors simultaneously, with epitopes sufficiently close to each other to permit the oligonucleotides conjugated to the second and third receptors to be ligated or amplified. Stearic hindrance would also serve to prevent affinity binding between the second and third receptors, as well as prevent amplification or ligation of the oligonucleotide labels attached to the receptors. The receptors recited in the claims are not limited to protein receptors, and carbohydrate, lipid and nucleic acid receptors are known in the art so any combination of three receptors would not serve as affinity reagents to simultaneously bind to and detect a single protein macromolecule. The claimed kits are not enabled for the detection of a protein macromolecule using three receptors. The person of skill in the art would de novo, be required to identify, what combination of three receptors would function as affinity reagents to detect a single macromolecule, as the instant specification has not described any combinations of receptors that would serve as affinity reagents with the recited abilities to bind in such close proximity. The instantly claimed kits that comprise three receptors is not enabled.

The instant specification also has not described, nor enabled the utilization of three nucleic acids to simultaneously bind to and detect a single protein macromolecule in a sample,

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wherein the protein macromolecule would bind to three different affinity reagent nucleic acids simultaneously, with epitopes/binding sites for the second and third nucleic acid affinity reagents sufficiently close to each other to permit the oligonucleotide conjugated thereto to be ligated or amplified. Nucleic acids are known in the art to bind to other nucleic acids and not to any protein macromolecule; any combination of nucleic acids would not serve as affinity reagents to simultaneously bind to and detect a protein macromolecule through amplification and ligation of the conjugate oligonucleotide labels attached thereto. The claimed kits are not enabled.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4 (claim 4 is dependent from claim 2) define the “macromolecule” to be “a specific antigen” and depends from claim 1 which defines the “macromolecule is a protein”. Claim 2 broadens the scope of claim 1, as all antigens are not proteins. Antigens are known to include carbohydrates, oxidized nucleic acids, lipopolysaccharides. This rejection could be obviated by amending the claims to recite --protein antigen--.

Claim 3 and 4 recites affinity reagents that are “lectins, receptors, Cofactors or nucleic acids”; Claim 3 broadens the scope of claim 1 from which it depends because:

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- a. lectins to do not bind to protein macromolecules, but to carbohydrates;
- b. the receptors are not defined to be protein macromolecule receptors;and
- c. the nucleic acids bind to nucleic acids not proteins.

7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

July 11, 2003

LFS
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600